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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,497	05/01/2001	Amina Odidi	9577-25 LAB	2340
7590 Lola A. Bartoszewicz Sim & McBurney 6th Floor 330 University Avenue Toronto, ON M5G 1R7 CANADA		02/07/2008	EXAMINER PRYOR, ALTON NATHANIEL	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 02/07/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/845,497

Applicant(s)

ODIDI ET AL.

Examiner

Alton N. Pryor

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6-9,11,15-17,21-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6-9,11,15-17,21-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's arguments filed 10/31/07 have been fully considered but they are not persuasive. See arguments below.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17,21,23,30,33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hirashima et al (JP 03197421; 8/28/91). Hirashima teaches a controlled release tablet coated with 12 g ethyl cellulose and 8 g PEG (40 %). Hirashima teaches that the tablet comprises 250 mg ascorbic acid and 281.23 mg sodium ascorbate (total active = 531.23 mg). The total active falls within the 5-95% active required for the tablet of instant claims. The coat comprising 12 g ethyl cellulose falls within the range of about 5 to less than 50% by weight of polymer in the coat. Hirashima does not teach that the coating is non-permeable and soluble in a pH of above about 5. However, in the absence of unexpected results, one having ordinary skill in the art would have expected for the prior art coat to be non-permeable and soluble in a pH of above about 5. One would have expected this since the prior art coat comprises % PEG and % polymer (ethyl cellulose) that fall within the ranges of those ingredients required by the instant claims.

Response to Applicant's argument

A. Applicant argues:

1. Instant encasement coat comprises at the high ends 50% polymer (ethylcellulose) and 40 % PEG; whereas, Hirashima teaching is an encasement coating comprising 60 % ethyl cellulose and 30 % PEG. In summary applicant argues that Hirashima does not teach or suggest the combination of about 5 to less than 50% by weight of polymer and 0.5%-30% by weight PEG that would provide a non-permeable which is soluble in a pH of above about 5 as claimed.
2. It would not be obvious to conclude that the coat of Hirashima would be non-permeable and soluble in a pH of above about 5.0. In fact Hirashima would be permeable and would not be soluble at any pH.
3. Instant invention requires a cellulose ester, whereas Hirashima employs ethylcellulose, which is not a cellulose ester. As a result, the coat taught by Hirashima would be permeable rather than non-permeable as claimed.
4. The polymer employed in Hirashima is ethyl cellulose. Ethyl cellulose is non-enteric meaning that it will dissolve at acidic pH. Therefore, an ethyl cellulose coating will dissolve to form pores at any pH in the gastric range and release its contents with no lag time. However, in instant invention, the extended release

composition claimed will remain intact until experiencing a pH above about 5 and will only then dissolve, providing an extended release of its contents. For this reason, an ethyl cellulose coating would not be applicable to this invention.

B. Examiner argues:

1. The amounts of PEG and ethylcellulose in Hirashima and instant invention differ only by 10% of each. Applicant does not provide a showing that the 10% difference would materially impact the invention. For this reason, the rejection of record is maintained.
2. Applicant makes statement to the coat of Hirashima being permeable and insoluble at any pH. However, Applicant does not provide data showing that the 10 % difference in both the ethylcellulose and PEG would make the coat non-permeable and soluble at a pH of about 5.0.
3. Ethyl cellulose is defined as being a cellulose ester having film-forming capability. See Google search attached.
4. Applicant makes statement that Ethyl cellulose is non-enteric meaning that it will dissolve at acidic pH. Therefore, an ethyl cellulose coating will dissolve to form pores at any pH in the gastric range and release its contents with no lag time. However, in instant invention, the extended release composition claimed will remain intact until experiencing a pH above about 5 and will only then

dissolve, providing an extended release of its contents. For this reason, an ethyl cellulose coating would not be applicable to this invention. However, the Applicant does not provide results to affirm the statement that ethyl cellulose would possess dissolution properties mentioned in Applicants argument above and therefore not be appropriate to meet the extended release limitation of the instant claims. Also according to the Goggle search provided to the Applicant in the previous office ethyl cellulose is a cellulose ester. For this reason ethyl cellulose would have been expected to meet the extended release properties of the instant claims.

In summary, Applicant argues that the amounts of PEG and polymer used in the polymeric film of Hirashima differ from the amounts of PEG and polymer used in the polymeric film disclosed in the instant invention. Applicant also argues that the polymeric film disclosed in instant invention is non-permeable whereas the polymeric film disclosed in Hirashima is semi-permeable. Examiner argues that the amount of both PEG and polymer taught in Hirashima and instant invention only differs by 10% and for this reason it is necessary for the Applicant to show the criticality of these small differences. With respect to the polymer properties, both Hirashima and instant invention employ the same polymers, e.g., cellulose esters. Therefore the cellulose ester taught in Hirashima which is semi-permeable, would have the same property of being semi-permeable in the instant invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,6-9,15-17,21-34 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for invention comprising polymeric films: polyvinyl acetate phthalate, methacrylic acid copolymers, does not reasonably provide enablement for the polymeric film being cellulose esters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Note instant invention requires the polymeric film to be non-permeable. The instant invention uses cellulose esters to formulate the non-permeable film. However USPN 6099859 at column 4 lines 10-28 and USPN 6106864 at column 4 lines 32-38 disclose that cellulose esters are semi-permeable rather than non-permeable.

Response to Applicant's argument

Applicant argues that Dolan (USPN 6106864) discloses that cellulose esters are semi-permeable rather than non-permeable. Dolan describes cellulose acetate as being both impermeable and semi-permeable. Applicant further argues "The cellulose esters chosen for the instant invention must be combined in the percentages claimed, and must provide the encasement coat with the features instantly claimed; be non-permeable and soluble in a pH of above about 5.0." Examiner argues that Applicant merely states that the correct percentages (claimed percentages) of cellulose esters

would provide a non-permeable coat, which would be soluble in a pH of above about 5.0. However, Examiner further argues that Applicant does not provide experimental results to show that such a coat would be produced. Where the prior art shows uncertainty or suggest the opposite of the claimed invention, it is critical that applicant supports the invention claimed with experimental data.

Applicant makes statement that Ethyl cellulose is non-enteric meaning that it will dissolve at acidic pH. Therefore, an ethyl cellulose coating will dissolve to form pores at any pH in the gastric range and release its contents with no lag time. However, in instant invention, the extended release composition claimed will remain intact until experiencing a pH above about 5 and will only then dissolve, providing an extended release of its contents. For this reason, an ethyl cellulose coating would not be applicable to this invention. However, the Applicant does not provide results to affirm the statement that ethyl cellulose would possess dissolution properties mentioned in Applicants argument above and therefore not be appropriate to meet the extended release limitation of the instant claims. Also according to the Google search provided to the Applicant in the previous office ethyl cellulose is a cellulose ester. For this reason ethyl cellulose would have been expected to meet the extended release properties of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,6-9,11,15-17,21-34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dolan et al (USPN 6106864; 8/22/00) and Dong et al (USPN 5800422; 9/1/98) and Cheng on record (USPN 6099859; 8/8/00). Dolan teaches oral dosage forms of actives such as darifenacin. See column 2 lines 34-52. Dolan teaches that the matrix comprising the active can be formed into a multiparticulate and / or coated with an impermeable coating. See column 2 lines 53-57. Dolan teaches that the multiparticulate cores comprising the actives can also contain cellulose and lactose (compression aids). See column 3 lines 1-7. Dolan teaches that the ingredients can be formulated into a tablet which can be coated with shellac, phthalate derivatives (cellulose acetate phthalate, polyvinylacetate phthalate) as well as with semi-permeable coatings such as cellulose esters (ethyl cellulose, cellulose acetate) and acrylic polymers. See column 3 lines 7-38. Dolan does not teach the polymeric coating comprising 1) 5 up to less than 50% by weight polymer, e.g. ethyl cellulose 2) 0.5 to 30% PEG. Dolan is silent to the amount of polymer in the coating. Therefore, in the absence of unexpected results showing the significance of the instantly claimed amount of polymer, the ideal amount of polymer used in Dolan may have fallen within the instant range of polymer amount being claimed. With respect to the polymeric film comprising PEG. Dong discloses the use of PEG in a capsule film coating. Note, Dong uses 25 % PEG in the polymer coating which falls within the instantly claimed range amount. Cheng teaches that PEG is a flux-enhancing agent. A flux-enhancing agent allows the

drug to be released through the pores of the polymeric coating. It would have been obvious to one having ordinary skill in the art to modify the invention of Dolan to include the PEG to enhance the release of the drug through the pores of polymeric coating. Although claims require the polymeric material to be non-permeable, it is noted that the claims employ polymeric films such as cellulose esters and acrylic polymers which are semi-permeable. For this reason the rejection appears to be proper. Note the property of the polymeric coating being soluble at a pH above 5.0 and having an extended release of the active over 12 hours are inherent properties of the polymer (cellulose esters) and PEG being used.

Response to Applicant's argument

Applicant argues:

- 1) Dolan teaches that impermeable coating is provided with an aperture. Ethyl cellulose is not a cellulose ester.
- 2) Dolan does not teach / suggest an encasement coat being non-permeable and soluble in pH of above about 5.
- 3) Declaration provided by Applicant on 3/8/04 shows that Cheng teaches the use of non-enteric cellulose esters and non-dissolving polymers and as a result Cheng's formulation yields a different release profile of the drug.
- 4) The specific percentage ranges instantly claimed provide unexpected results in comparison to Cheng and hence, in comparison to Dolan since similar coatings are used in Dolan.

Examiner argues:

1) Dolan teaches that the coating can be made using ethyl cellulose. None that the instant claims recite that the coating can comprise ethyl cellulose. According to a Google search ethyl cellulose is a cellulose ester possessing film-forming properties.

2) Dolan teaches that the coating can be formed of ethyl cellulose which produces a semi-permeable coating as depicted in column 3 lines 31-38 of Dolan. Dolan also teaches that ethyl cellulose can be employed to form an impermeable coat as depicted in column 3 lines 11-21. There is no mention of a non-permeable coat in Dolan as recited in the claims. Since ethyl cellulose can be used to form impermeable as well as semi-permeable coats, it would be necessary for applicant to show what kind of coating is produced with the specific percentages claimed. Note Dolan does not teach or suggest a non-permeable membrane. Dolan defines an impermeable membrane as one that allows no significant transport of the active across it during the intended release period of the formulation. See column 3 lines 11-21. Dolan defines semi-permeable membrane as one that allows transport of an active across it. See column 3 lines 31-38. Again, Dolan does not make mention that the ingredients employed therein would produce a non-permeable membrane. In fact the formulation of a non-permeable membrane is not even mentioned in Dolan. For this reason, it is imperative that Applicant shows that his invention produces a non-permeable membrane using a cellulose ester since Dolan only teaches the production of impermeable and semi-permeable membranes using ethyl cellulose. Note Google defines ethyl cellulose as a cellulose ester.

3) The combination of Dolan with Dong and Cheng yields a coating comprising ethyl cellulose (cellulose ester) and PEG in the percentage ranges claimed. As a result it would be inherent for the properties of the coat produced by the combination of the references to have the same properties as the coat produced in the instant claims, i.e. non-permeable and soluble at a pH of above about 5.0. Note, Dolan and Dong produces a coating comprising ethyl cellulose and PEG. Cheng is being employed in the rejection to show the significance of PEG as a flux-enhancing agent.

Applicant makes statement that Ethyl cellulose is non-enteric meaning that it will dissolve at acidic pH. Therefore, an ethyl cellulose coating will dissolve to form pores at any pH in the gastric range and release its contents with no lag time. However, in instant invention, the extended release composition claimed will remain intact until experiencing a pH above about 5 and will only then dissolve, providing an extended release of its contents. For this reason, an ethyl cellulose coating would not be applicable to this invention. However, the Applicant does not provide results to affirm the statement that ethyl cellulose would possess dissolution properties mentioned in Applicants argument above and therefore not be appropriate to meet the extended release limitation of the instant claims. Also according to the Goggle search provided to the Applicant in the previous office ethyl cellulose is a cellulose ester. For this reason ethyl cellulose would have been expected to meet the extended release properties of the instant claims.

New Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,6-9,11,15-17,21-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6676966. Although the conflicting claims are not identical, they are not patentably distinct from each other because both instant invention and USPN '966 make claim to composition comprising an active ingredient and an encasement coat in a pH sensitive polymeric film for the encasing of the active; wherein the polymeric film is soluble at a pH of about above 5.0. See USPN 966 claim 1. USPN '966 makes claim that the composition can comprise 5 to 95 % active (see USPN '966 claim 2) and that the composition can exist in a variety of physical forms including tablets, pellets and capsules (see USPN '966 claim 3) as instantly claimed. USAN '966 makes claim that the composition can comprise plasticizers such as polyethylene glycol (see USPN '966

claims 11 and 12) as instantly claimed. The instant claims differ from the claims in USPN '966 in that instant claims are limited to the pharmaceutical composition existing only as a tablet, capsule or pellet, whereas claims in USPN '966 discloses that the composition can exist as a formulation which is not limited to tablet, capsule or pellet form. Since USPN '966 makes claim that the composition can exist as a tablet, capsule or pellet, the instant claims are made obvious over USPN '966.

Claim 33 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2,6 of U.S. Patent No. 6652882. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the USPN '882 and instant invention make claim to a controlled release composition comprising an active and film coat (encasement coat). USPN '882 does not express that the coat has to be non-permeable and soluble in a pH of above about 5.0 However, it would have been obvious to employ a coat that would have met the non-permeable and solubility limitation. One would have been motivated to do this since USPN '882 disclose generically a film coat.

Claim 33 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,4,5 of U.S. Patent No. 6509037. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the USPN '037 and instant invention make claim to an extended release composition comprising an active and film coat (encasement coat). USPN '037 does not express that the coat has to be non-permeable and soluble in a pH of above about 5.0 However, it would have been obvious to employ a coat that would

have met the non-permeable and solubility limitation. One would have been motivated to do this since USPN '037 disclose generically a film coat.

Claim 33 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,5 of U.S. Patent No. 6312724. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the USPN '724 and instant invention make claim to a controlled release composition comprising an active and film coat (encasement coat). USPN '724 does not express that the coat has to be non-permeable and soluble in a pH of above about 5.0. However, it would have been obvious to employ a coat that would have met the non-permeable and solubility limitation. One would have been motivated to do this since USPN '724 disclose generically a film coat.

Claim 33 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6296876. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the USPN '876 and instant invention make claim to a controlled release composition comprising an active and enteric coat (encasement coat). USPN '876 does not express that the coat has to be non-permeable and soluble in a pH of above about 5.0. However, it would have been obvious to employ a coat that would have met the non-permeable and solubility limitation. One would have been motivated to do this since USPN '876 discloses generically an enteric coat.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Alton Pryor
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